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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/071,052	06/04/1993	JEFFRY W. KREAMER	467312465	9541

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DAVIS, BROWN, KOEHN, SHORS & ROBERTS, P.C.  
THE FINANCIAL CENTER  
666 WALNUT STREET  
SUITE 2500  
DES MOINES, IA 50309-3993

EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/071,052

Applicant(s)

KREAMER, JEFFRY W.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-31 is/are rejected.
- 7) ☒ Claim(s) 27 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **CLAIMS 1-31 ARE PRESENTED FOR EXAMINATION**

The request filed on January 10, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/071,052 is acceptable and a CPA has been established. An action on the CPA follows.

### **STATUS OF THE CLAIMS**

Claims 27 and 28 could not be replaced as the applicant requested but were inadvertently referred as such by the applicant. They have been entered as new claims and renumbered as 30 and 31 under 37 C.F.R. 1.126. Applicant is requested to cancel claims 28 and 29 filed December 1, 1999.

Applicant's election of the composition claims of 27-29 submitted in Paper No. 17, filed December 1, 1999 is acknowledged and the paper has been entered. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore the status of the claims is as follows:

1. Claims 1-31 are presented for examination.
2. Original claims 27 and 28 filed December 1, 1999 are objected to and should be canceled.
3. Claims 1-26 drawn to a method of use, subject to being rejoined if it is determined that there are allowable claims, are withdrawn from consideration.
4. Claims 29-31 have been examined.

**REJECTION UNDER 35 U.S.C. 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 29-31 are rejected under 35 U.S.C. 102(a) or (f) as being anticipated by the unpublished observational study conducted by the University of Southern California (specification page 14) and applicant's admissions.

The data appears to show the concept of combining aspirin and multivitamin was known to a party other than the inventor at the time the application was filed. While applicant states that the data is unpublished, the data represents prior art under 35 U.S.C. 102(a) and/or 102(f). Also, the declaration by Larry H. Hollier, MD (paper no. 5 and attachment 7 of the brief) acknowledges that multivitamins are the most typical type of over-the-counter vitamins taken by the general public and that such vitamins are typically administered in tablet form and typically contain the elements claimed by applicant (declaration paragraphs 12 and 13). Moreover on page 6 of the specification. Applicant states that "aspirin is an anti-inflammatory agent which is known in the art to irreversibly block platelet prostaglandin (sic,prostaglandin) function". Applicant further acknowledges that it is within the skill of the art to orally administer dosages of aspirin to block prostaglandin function in platelets and to orally administer dosages of minerals or vitamins to reduce the migration of cholesterol into the endothelium, and that the amounts of such dosages are well known to the art (specification: p. 2-4, 6-12; brief:

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p.6). The amount of aspirin and the vitamin would be variables. Optimization of such variables in a combined dosage may be recognized in the prior art to be a result effective variable would ordinarily have been within the skill in the art. In re Boesch, 67 F. 2d 272, 205 USPQ 215 (CCPA 1980). In addition, the specification is replete with citation to published research of others to demonstrate the properties summarized in tables 1 and 2 of applicant's specification (see pp. 1-12).

Each of the admissions discloses that a composition of multiple vitamins is well known to the art. Applicant's claims being open-ended are anticipated under the cited statute. It is well-established that a new composition for a claimed use is not patentable.

In view of the above it is deemed that the rejection under 35 USC 103 (a) and /or (f) is deemed proper.

#### **REJECTION UNDER 103**

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the unpublished observational study conducted by the University of Southern California

The rejections set forth above are reasserted here with full force and effect to establish a prima facie case of obviousness under 35 U.S.C. 103(a) since it would be obvious to combine the claimed vitamins in combination since such combinations are known to the art as admitted by applicant.

There is a lack of criticality as to the claimed combination set forth in the specification and it was common practice prior to applicant's filing date for a person to take a multivitamin and aspirin simultaneously or concurrently. The Examiner will

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supply an affidavit or declaration of this fact if applicant fails to take Judicial Notice thereof.

Applicant's allegation that a synergism has been established with the claimed combination as set forth in claims 29-31 (which claims are open-ended in using the term "comprising") has not been clearly defined or explained by applicant. In Table 3 it is unclear as to which vitamins are being tested to yield the desired result.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness is presented

#### **Rejection under 35 USC 112, second paragraph**

This rejection is withdrawn in accordance with the Remand by the Board of Patent Appeals and Interferences dated September 16, 1998.

#### **CONCLUSION**

Claims 29-31 are rejected.

Applicant is to provide the following:

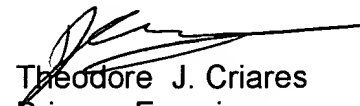
1. Information regarding the compositions set forth in unpublished University of Southern California Report:
  - a) date the compositions were prepared;
  - b) Names of the individuals who prepared the compositions.
2. Explain how Tables 2 and 3 establish a synergistic effect.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moeizie can be reached on 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

T.J.C.  
July 18, 2002